IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., ***Plaintiff*,** ***v.*** **BIONPHARMA INC.,** ***Defendant*.**	**Civil Action** **Nos. 21-cv-1286, 21-cv-1455**

MEMORANDUM OPINION

Goldberg, J.[1] **January 6, 2023**

These cases comprise what the parties refer to as the "Third Wave" in an ongoing patent infringement dispute between Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity") and Defendant Bionpharma Inc. ("Bionpharma"). The parties' dispute revolves around Bionpharma's generic enalapril oral liquid. The First Wave of this litigation ended with a judgment of noninfringement for Bionpharma following a bench trial before the Honorable Leonard Stark. Thereafter, the Second Wave was dismissed by stipulation.

Presently before me is Bionpharma's motion for judgment on the pleadings, wherein Bionpharma asserts that the First and Second Wave judgments preclude Azurity's claims in the Third Wave. For the reasons set out below, Bionpharma's motion will be denied, as will its request to certify this ruling for interlocutory appeal.

[1] Pursuant to 28 U.S.C. § 292(b), I have been designated to serve as a visiting judge for the District of Delaware to handle this matter and other District of Delaware cases.

I. FACTUAL AND PROCEDURAL BACKGROUND

The material facts are undisputed. In May of 2018, Azurity sued Bionpharma in what would become the "First Wave" of patent infringement litigation over Bionpharma's Abbreviated New Drug Application (ANDA) for an oral liquid formulation of the blood pressure medicine enalapril. The First Wave involved U.S. Patent Nos. 9,669,008, 9,808,442, 10,039,745, and 10,154,987 (collectively the "First Wave patents"). On April 27, 2021, Judge Stark entered judgment for Bionpharma after a bench trial in the First Wave, finding that Bionpharma's ANDA did not infringe the First Wave patents because, among other reasons, Bionpharma's ANDA does not contain the buffer that the First Wave claims require. (See No. 19-1067, Docket Entry 244.)

The Second Wave lawsuit involved U.S. Patent Nos. 10,772,868, 10,786,482, and 10,918,621 (the "Second Wave patents"). The accused product was unchanged between the First and Second wave suits and remained Bionpharma's ANDA for enalapril liquids. After judgment in the First Wave became final on appeal, Azurity stipulated to dismissal of the Second Wave lawsuit.

The present lawsuits comprise the Third Wave and involve U.S. Patent Nos. 11,040,023 and 11,141,405 (the "Third Wave patents"). The accused product remains Bionpharma's ANDA.

The First, Second, and Third wave patents describe enalapril liquids. While the claims have some elements in common, they differ with respect to whether the claimed liquids must contain buffers. Each claim of the First and Second Wave patents requires a buffer. The following is illustrative:

> A stable oral liquid formulation, consisting essentially of:
>
> (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
>
> (ii) a buffer to maintain the pH about 4.5 or below, wherein the buffer con-

centration is about 5 mM to about 20 mM;
(iii) about 1 mg/ml of a preservative that is sodium benzoate; and
(iv) water;

wherein the formulation optionally comprises a sweetener, a flavoring agent, or both;

wherein the formulation is stable at about 5 ± 3° C. for at least 12 months; and

wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

(Claim 1 of U.S. Patent No. 10,772,868 (emphasis added).)

By contrast, the claims of the Third Wave patents do not require a buffer:

A stable oral liquid formulation, consisting essentially of:

(i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
(ii) a sweetener;
(iii) a preservative, wherein the preservative comprises sodium benzoate, a paraben or a mixture of parabens;
(iv) water; and
(v) optionally a flavoring agent;

wherein the formulation is stable at about 5 ± 3° C. for at least 12 months; and

wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

(Claim 1 of U.S. Patent No. 11,040,023.)

The First, Second, and Third wave lawsuits were reassigned to me on March 2, 2022. Bionpharma now moves for judgment on the pleadings, asserting that the judgment of noninfringement in the First Wave suits and subsequent stipulation of dismissal in the Second Wave are preclusive of Azurity's infringement claims in the Third Wave suits.

II. LEGAL STANDARD

A motion under Federal Rule of Civil Procedure 12(c) for judgment on the pleadings will be granted only if "the movant clearly establishes that no material issue of fact remains to be resolved

and that [the movant] is entitled to judgment as a matter of law." Rosenau v. Unifund Corp., 539 F.3d 218, 221 (3d Cir. 2008). In deciding the motion, the court must accept the nonmoving party's factual allegations as true and view them in the light most favorable to the nonmoving party. Id.

III. DISCUSSION

The parties primarily agree on most of the facts central to their current dispute and disagree only on the applicable test for determining whether two patent infringement claims are the "same cause of action" for purposes of claim preclusion. For the reasons set out below, I agree with Azurity that the applicable test is whether "the scope of the asserted patent claims in the two suits is essentially the same." SimpleAir, Inc. v. Google LLC, 884 F.3d 1160, 1167 (Fed. Cir. 2018). Applying that test, I conclude that the Third Wave suits do not involve the same cause of action as the First and Second Wave suits.

A. Claim Preclusion

"[C]laim preclusion … gives dispositive effect to a prior judgment if a particular issue, although not litigated, could have been raised in the earlier proceeding." CoreStates Bank, N.A. v. Huls America, Inc., 176 F.3d 187, 194 (3d Cir. 1999) (emphasis in original, quotation marks deleted). "Claim preclusion requires: (1) a final judgment on the merits in a prior suit involving; (2) the same parties or their privities; and (3) a subsequent suit based on the same cause of action." Id. "If these three factors are present, a claim that was or could have been raised previously must be dismissed as precluded." Id.

For purposes of the present motion, the parties agree that the First Wave judgment of noninfringement and the Second Wave stipulation of dismissal are final judgments on the merits in prior suits involving the same parties. Thus, the only dispute is whether the Third Wave suits involve the

"same cause of action" as the First and Second wave suits.

1. Whether Two Infringement Claims are the "Same Cause of Action"

"[A] cause of action [is defined] based on the transactional facts from which it arises." SimpleAir, 884 F.3d at 1165. "If the overlap between the transactional facts of the suits is substantial, the later action should ordinarily be precluded." Id. "In a patent suit, essential transactional facts include both the asserted patents and the accused activity." Id. Thus, preclusion will apply when: (1) "the accused activity between two cases [is] 'essentially the same' "; and (2) "the scope of the asserted patent claims in the two suits is essentially the same." Id. at 1167.

There is no dispute here that the accused infringing activity is identical between the First, Second, and Third wave suits. (Azurity does not argue that the addition of a damages claim in the Third Wave makes any difference.) The only disagreement is whether "the scope of the asserted patent claims" among the First, Second, and Third wave patents "is essentially the same."

In Azurity's view, that question should be answered by comparing the scope of the claims from the First and Second wave patents to the scope of the claims from the Third Wave patents. Azurity posits that because each claim of the First and Second Wave patents requires a buffer, and each claim of the Third Wave patents does not require a buffer, the claims of the Third Wave patent cover different scope. Thus, according to Azurity, "the scope of the asserted patent claims" is not "essentially the same," and claim preclusion does not apply.

Bionpharma disagrees with Azurity's proposed test based on claim scope. Bionpharma instead asks me to import a test from the law of "obviousness-type-double-patenting" and apply that test to the doctrine of claim preclusion. According to Bionpharma's proposed test, two patent claims are "essentially the same" if the second claim would have been obvious to one skilled in

the art with knowledge of the first claim. (See Bionpharma's Brief at 12.) Because the Third Wave claims are largely the same as the First and Second Wave claims, except for the removal of the buffer, Bionpharma argues that the Third Wave claims would have been obvious to a person of ordinary skill in the art with knowledge of the First and Second Wave claims. Therefore, according to Bionpharma's test, the Third Wave claims are "essentially the same" as the First and Second Wave claims, and claim preclusion bars the Third Wave suits.

The parties' divergent positions stem from the following sentence in the Federal Circuit's SimpleAir decision: "In applying [the claim preclusion] standard to the particular context here, we conclude that claims which are patentably indistinct are essentially the same." SimpleAir, 884 F.3d at 1167 (emphasis added). The underlined term "patentably indistinct" is also used in the doctrine of obviousness-type double patenting, where it means that "the [later] claims are obvious over the [earlier] claims." In re Basell Poliolefine Italia S.P.A., 547 F.3d 1371, 1375 (Fed. Cir. 2008). Bionpharma argues that by using the term "patentably indistinct," the Federal Circuit imported the test for obviousness-type double patenting into the claim preclusion context. For the following reasons, I disagree with Bionpharma's reading of SimpleAir:

First, the Federal Circuit has interpreted SimpleAir differently than how Bionpharma advocates. In XY, LLC v. Trans Ova Genetics, LC, 968 F.3d 1323 (Fed. Cir. 2020), the Federal Circuit quoted SimpleAir for the proposition that "a judgment in the first suit will trigger claim preclusion only if the scope of the asserted patent claims in the two suits is essentially the same." Id. at 1333. In Indivior Inc. v. Dr. Reddy's Labs., S.A., 930 F.3d 1325, 1336 (Fed. Cir. 2019), the court similarly characterized SimpleAir, citing it only for the proposition that claim preclusion turns on whether the claims are "essentially the same." Notably, in both cases, the Federal Circuit did not cite SimpleAir as importing a test from obviousness-type double patenting or quote SimpleAir's

use of the term "patentably indistinct." While a prior non-precedential Federal Circuit opinion in Indivior did quote SimpleAir's use of the term "patentably indistinct," that decision did not apply the test from obviousness-type double patenting and actually concluded that the claims were likely patentably indistinct only because "the scope of the claims did not materially change." Indivior Inc. v. Dr. Reddy's Labs., S.A., 752 F. App'x 1024, 1035 (Fed. Cir. 2018) (emphasis added). The Federal Circuit therefore does not read SimpleAir's reference to patentably indistinct claims as importing the test from obviousness-type double patenting.

Second, other statements in SimpleAir show that the test for claim preclusion differs from the test for obviousness-type double patenting. If the two tests were the same, features that are true for one test would also be true for the other test, but this is not the case. As set out in SimpleAir, claim preclusion can be avoided if the later-asserted claims "provide larger claim scope" than the earlier-asserted ones. 884 F.3d at 1167. But obviousness-type double patenting is not avoided when the later claims are broader in scope than the earlier claims. In re Goodman, 11 F.3d 1046, 1053 (Fed. Cir. 1993). Because broadening claim scope avoids the test for preclusion but not the test for obviousness-type double patenting, the two tests are not interchangeable.

Third, to the extent SimpleAir impliedly referenced the test for obviousness-type double patenting, that reference was unnecessary to the outcome and therefore dictum. See National American Ins. Co. v. United States, 498 F.3d 1301, 1306 (Fed. Cir. 2007) (finding the lower court was "correct" to treat unnecessary statements as dicta). In SimpleAir, the Federal Circuit reversed a district court ruling that a terminal disclaimer (a device used to overcome obviousness-type double patenting) was dispositive on the issue of claim preclusion and directed the district court to redo the analysis based on "the scope of the [asserted] claims in comparison with the patents litigated [previously]." See SimpleAir, 884 F.3d at 1166. The Circuit Court did so, in part, because a

terminal disclaimer is not dispositive of double-patenting and thus a fortiori not dispositive of claim preclusion. Id. at 1167-68. That reasoning holds regardless of whether the reference to patentably indistinct claims imported the test from obviousness-type double patenting. While I have carefully considered this dictum from the Federal Circuit, I must defer to the consistent holding of that court that the test for claim preclusion turns on the scope of the asserted claims. See XY, 968 F.3d at 1333; Indivior, 930 F.3d at 1336; SimpleAir, 884 F.3d at 1167.

Lastly, Bionpharma urges me to adopt its reading of SimpleAir based on district court decisions that merely quote SimpleAir's reference to patentably indistinct claims. See Corning Inc. v. Wilson Wolf Manufacturing Corp., 569 F. Supp. 3d 920, 933-34 (D. Minn. 2021); Kol-craft Enterprises, Inc. v. Artsana USA, Inc., No. 13-cv-4863, 2020 WL 1491142, at *5 (N.D. Ill. March 27, 2020); Puget Bioventures, LLC v. Biomet Orthopedics LLC, No. 17-cv-502, 2018 WL 2933733, at *3 (N.D. Ind. June 11, 2018). But in none of these cases did the district court actually perform the test from obviousness-type double patenting. Tellingly, the district court on remand from SimpleAir itself concluded that the Federal Circuit "did not create a new standard requiring a showing of anticipation or obviousness to satisfy claim preclusion." Google LLC v. SimpleAir, Inc., No. 16-cv-3758, 2020 U.S. Dist. LEXIS 172293, at *15 (C.D. Cal. Aug. 20, 2020).

For these reasons, I conclude that the proper test for determining whether claim preclusion applies is whether "the scope of the asserted patent claims in the two suits is essentially the same." SimpleAir, 884 F.3d at 1167.

2. Application to the First, Second, and Third Wave Suits

Applying the above test, there is no dispute that the Third Wave claims cover scope not covered by the First and Second wave claims. Eliminating the buffer limitation allows the claims

to encompass enalapril liquids that do not contain buffers. That distinction is material because it impacts two of the three grounds on which Judge Stark found noninfringement in the First Wave—those are, that Bionpharma's ANDA did not infringe because it did not contain a buffer and because it did not contain an equivalent to a citrate buffer. The lack of a buffer limitation in the Third Wave claims is also significant because it underlies Bionpharma's defense in this case that the patents' written specification does not adequately describe liquids without buffers.

The scope of the Third Wave claims is therefore not "essentially the same" as the scope of the First and Second Wave claims. For that reason, claim preclusion does not apply.

B. The Kessler Doctrine

Bionpharma also argues that, if claim preclusion does not apply, the Kessler doctrine should nevertheless operate to bar some portion of Azurity's infringement claims in the Third Wave. "[T]he … Kessler doctrine … preclude[s] assertion[] of a patent against … post-judgment activity if the earlier judgment held that 'essentially the same' accused activity did not infringe that patent." SimpleAir, 884 F.3d at 1170. But the Kessler doctrine does not "bar a broader set of rights than would be barred by claim preclusion." Id. (emphasis in original). Because claim preclusion does not bar the set of rights contained in the Third Wave patents, the Kessler doctrine does not either.

IV. CONCLUSION

For the reasons set out above, Bionpharma's motion for judgment on the pleadings will be denied.

Bionpharma asks me to certify this ruling for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). Because I conclude that there is no "substantial ground for difference of opinion" as

to whether the test for obviousness-type double patenting applies to claim preclusion, I will not certify this ruling for interlocutory appeal. See id.

An appropriate order follows.